A COMPARATIVE STUDY OF THE EFFICACY OF INTRAVAGINAL MISOPROSTOL WITH EXTRAAMNIOTIC BOUGIE IN SECOND TRIMESTER MEDICAL TERMINATION OF PREGNANCY

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CERTIFICATE

Certified that this dissertation entitled " A COMPARATIVE STUDY OF THE EFFICACY OF INTRAVAGINAL MISOPROSTOL WITH EXTRAAMNIOTIC BOUGIE IN SECOND TRIMESTER MEDICAL TERMINATION OF PREGNANCY " is a bonafide work done by **Dr.P.VISHNUPRIYA, M.D.,** Post Graduate Student of OBSTETRICS AND GYNAECOLOGY,under my overall supervision and guidance at the Institute of social Obstetrics and Government Kasturba Gandhi Hospital for Women and Children, Madras Medical College and Research Institute, Chennai, in partial fulfillment of regulations of Tamilnadu Dr. M.G.R. Medical University for the award of M.D degree in Obstetrics and Gynaecology during the academic year 2005 - 2008.

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INTRODUCTION

Abortion is the termination of pregnancy before the fetus has attained the stage of viability. This was originally fixed at 28 weeks, which corresponds to a fetal wt of 1000gm. With expert neonatal care, this limit has been brought down to 20 weeks of pregnancy, corresponding to fetal wt of 500gm in developed countries.

Abortion may be spontaneous or induced. Induced abortions are deliberately caused and these may be legal or illegal.

Unsafe abortions are those, which are performed by untrained persons and/or improperly equipped institution and are more likely to result in maternal morbidity and/or mortality.

The proportion of abortions ranges from 9-15% of total pregnancies. The actual incidence of abortion worldwide is not known but estimates range from 40-60 million a year of which atleast half are unsafe.[1] Nearly 40-50/1000 women of reproductive age have abortion annually with an abortion ratio of 260-450/1000 live births.

In India, it is estimated that about 6 million abortions take place every year of which 2 million are spontaneous and 4 million are induced. Of the

induced abortions, only about 5 – 6 lakhs are legal and rest are estimated to be illegal abortions.

Where abortions are legal and statistics are accurate, the mortality ratio ranges from 1-3.5 per 1,00,000 abortions in the developed countries. In India, the mortality is reported to be 7.8 per 1000 abortions, most of which are illegal.

Illegal abortions are a frequent cause of severe short term and long term sequelae.

The most common early complications are:

1) excessive blood loss
2) pelvic infection
3) uterine perforation
4) cervical injury.
5) thromboembolism
6) shock
7) anaesthetic complications.

The late sequelae include infertility and ectopic pregnancy.

Medical termination of pregnancy (MTP) is the voluntary medical or surgical removal of a pregnancy before the period of viability.

The laws governing the induction of abortion have changed over the years and these changes were motivated by a need to

(i) Eliminate the practice of criminal abortion.

(ii) To remove unwanted and unplanned pregnancies.

(iii) To avoid the social and psychological stress associated with the birth of an unwanted baby to an unmarried mother.

(iv) To abolish illegitimate off spring.

(v) Provide an additional means of family planning and population control.

The MTP act was introduced in India in 1971 as a maternal health measure and not a birth control measure;[2] and the act was amended in 2002.

In spite of availability of safe and effective contraceptive methods, couples fail to use them and come for MTP, even in the second trimester, when the risks of infection and surgical intervention are high. This tendency is particularly high amongst the unmarried and the undecided. Until recently one of the best known and highly popular method of II trimester abortion is the introduction of bougie – a thick rubber tubing – extra amniotically for the induction of abortion.

Medical abortion, by virtue of it being simple, safe and effective and without the risks of invasive procedures and anaesthesia is becoming the method of choice in many centres and has successfully replaced bougie in most of the places; the success rate is also as high as 95%.[3]

The introduction of prostaglandin analogues in the late 1970's changed the management of termination of pregnancy in 2nd Trimester. The subsequent introduction of antiprogestin, mifepristone, shortened the induction abortion interval and reduced the dosage of misoprostol required though the cost of Mifepristone and misorpostol combination is still high and is not affordable by many in a resource poor setting.

Hence there are still places where extra amniotic instillations are being practiced and bougie remains a popular method of choice in these places.

This study compares the efficacy of misoprostol to the bougie insertion in 200 cases who came for second trimester termination of pregnancy at the Institute of Social Obstetrics and Government Kasturba Gandhi Hospital, Chennai and approved by hospital ethical committee

The MTP Act [4, 5, 6]

In India, the medical termination of pregnancy act was passed by the parliament in 1971 and came into force on 1st April 1972. The act liberalized the abortion law as a family welfare and health measure to ensure better health and prevent risks to the life of women from hazards of criminal abortion.

Medical termination of pregnancy is permitted under the law up to 20 weeks of gestation, but not beyond.

Grounds for performing MTP:

Medical grounds: when the continuation of pregnancy is likely to

(i) Endanger the life of the pregnant women.

(ii) Cause grievous injury to her physical or mental health as in severe hypertension, diabetes, cardiac disease, psychiatric illness, genital and breast cancer.

Eugenic grounds:

When there is substantial risk of the child being born with serious physical or mental abnormalities.

- Hereditary disorders.
- Congenital malformation in previous offspring with high risk of recurrence.
- Rh iso-immunization
- Maternal rubella posing risk of anomalies in the fetus.

Humanitarian grounds:

When pregnancy is caused by rape or incest.

Social grounds:

When

(i) her socio economic status might lead to risk of injury to her health.

(ii) Pregnancy resulting from failure of contraception- temporary (or) permanent method.

Persons who can perform MTP:

The act authorises only a registered medical practitioner having experience in obstetrics and Gynecology to perform abortion where the length of pregnancy does not exceed 12 weeks; where the pregnancy exceeds 12 weeks and not more than 20 weeks, the opinion of 2 Registered Medical Practitioners is necessary to terminate the pregnancy.

Qualifications required to do abortion:

The doctor is qualified to do MTPs if he/she has one or more of the following qualifications.

(i) if he has assisted a Registered Medical Practitioner in the performance of 25 cases of MTP in an approved institution.

(ii) 6 month of housemanship in obstetrics & gynecology

(iii) A postgraduate qualification in obstetrics and gynecology.

(iv) 3 yrs of practice in OBG for those doctors registered before the 1971 MTP act was passed.

(v) 1 year of practice in OBG for those doctors registered on or after the commencement of the act.

Place for performing MTP:

(i) A hospital established and maintained by the government.

(ii) A place recognised and approved by the government, under this act.

The women undergoing MTP should be educated to accept contraception but is not mandatory.

Objectives of counselling for MTP:

- Helping the woman to understand her options regarding the pregnancy, whether to proceed with abortion or not.
- Informing the woman of the possible risks and possible complications.
- Discussing the likelihood of successful treatment .
- Discussing future fertility regulation.

The MTP (amendment) act 2002:

The act mainly aims at reducing the rate of unsafe abortions by making legal abortion more widely accessible. Lack of access to MTP services at primary health care level is an important reason for increased rate of unsafe and illegal abortions. The amendment is aiming at decentralization of authority for approval and registration of MTP centers from state to district level.

Methods for induction of abortion according to gestational period:

Length of Amenorrhea	Technique
<9 weeks	Antiprogestins or prostaglandins, Vacuum aspiration
9 – 14 weeks	Vacuum aspiration (with cervical preparation particularly after 12 weeks and in nulliparous woman)
>14 weeks	1) Antiprogestins + PG 2) Prostaglandins alone 3) Hypertonic saline, Urea, Ethacridine lactate 4) D&E (with cervical preparation)

Methods of 2nd Trimester MTP:[7]

Medical methods:

1.	**Intra amniotic instillation of drugs:**	
	(i)	20% hypertonic saline
	(ii)	Hypertonic glucose
	(iii)	Urea
	(iv)	Prostaglandin
2.	**Extra ovular instillation of drugs:**	
	(i)	0.1% Ethacridine lactate
	(ii)	Hypertonic saline
	(iii)	Prostaglandins
	(iv)	Mifepristone and Misoprostol
3.	**Extra uterine methods:**	
	(i)	PGF 2 alpha IM
4.	**Extra ovular insertion of devices**	
	(i)	sterile catheters
	Surgical methods:	
	1)	Dilatation and Evacuation [8, 9, 10]
	2)	Aspirotomy
	3)	Hysterotomy

Medical abortion

If is the use of drugs for induction of abortion. The introduction of PG analogues and mifepristone has changed the management of second trimester abortion in the last 2 decades; PG analogues are associated with less side effects when compared with oxytocin infusion, hypertonic saline or urea; the application of PG analogues for medical abortion is simple does not require trained expertise; while surgical abortion [8,9,10] requires.

(i) Hospital or good clinics for performing the procedure.

(ii) Anaesthesia.

(iii) Cervical preparation with misoprostol, mifepristone, laminaria tents or mechanical dilatation.

and associated with higher chances of

1) repeated abortions

2) premature labour

3) cervical incompetence

4) secondary infertility

The following strategies can be adopted to make medical abortion feasible in India;

1) Continue clinical / acceptability studies;

This will allow the provider to gain expertise and know that women like the method.

2) Conduct non-clinical studies;

Qualitative research should document women's experience and assess provider's knowledge and experience.

3) Increase provider knowledge;

Medical abortion training centres should be established or training for medical abortion be incorporated in existing surgical MTP training courses and flexibility is to be incorporated in national guidelines to facilitate adoption of evidence based regimens.

4) Increase client knowledge;

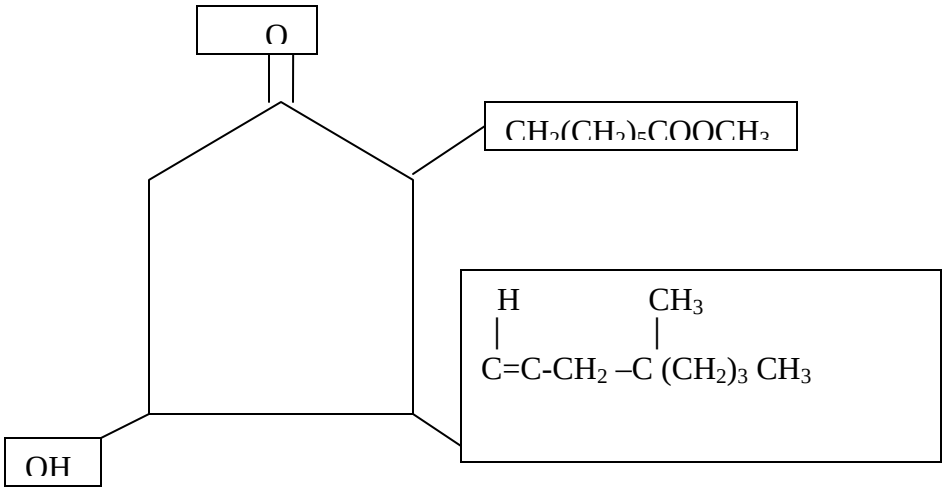
By appropriate media outlets (i.e) women's magazines, talk/radioshows and school health talks.

5) document serious adverse effects;

Serious adverse events should be added to monthly MTP reporting by registered provider.

MISOPROSTOL

Chemical Structure of Misoprostol



Chemical Structure of Misoprostol

Naturally occuring PGE_1, is not orally sustainable as it is unstable in acid media, and also not suitable for parenteral use because of its rapid degradation in the blood.

Synthetic PGE_1, analogue, has been produced by bringing about an alteration in the chemical structure of this naturally occuring compound. The chemical formula of misoprostol is $C_{22}H_{38}\ 0_5$ (or) Methyl (13E) – 11, 16-Dihydroxy – 16 – Methyl – 9 – OXO – Prost. – 13 – Enoate.

Misoprostol is manufactured as 100 and 200 mg. tablet and can be used orally, vaginally and rectally. This drug is very stable in ambient temperature and has a long shelf life.

Following oral administration this drug absorbed quickly and de-esterished to be converted into its active pharmacological form misoprostol acid. Concentration of this metabolite reaches its peak in plasma by 30 minutes and declines rapidly half life 21 minutes)[11]

Primary site of metabolism of this drug is in liver and less than 1 percent of this metabolite is excreted in urine. Dose of the drug needs adjustment when used in patients with liver disease whereas it is not required in patient with renal disease and not on dialysis.[12]

Misoprostol does not affect hepatic mixed function oxidase (cytochrome P – 450) enzyme system.

Vaginal administration has the advantage of reducing gastrointestinal side effects and exerts profound effect on reproductive tract.[13] After application in the posterior fornix, plasma concentration reaches peak by one to two hour and then slowly declines.

After oral and vaginal administration of this drug, intrauterine pressure begins to increase by 8 and 25 minutes and reached maximum by 25 and 46

minutes respectively. Maximum uterine contractility was significantly higher after vaginal administration.[14]

Cumulative dose upto 2200 mg has been found to be tolerated by expectant mothers with no serious side effects when administered over 12 hours

This drug has common adverse effects like nausea, vomiting, diarrhea, abdominal pain,chill, shivering and fever which are does dependent. Myocardial infarction and bronchospasm has not been reported yet with misoprostol.[15]

Teratogenicity:

Congenital facial paralysis (moebius' syndrome) and limb defects have been reported in infants of women who ingested misoprostal in first trimester in an unsuccessful attempt to induce abortion.[16] In a recent case control study, malformations like transverse limb defects, ring shaped construction of the extremities, arthrogryposis, hydrochephalus, holoprosencephaly and exstrophy of the bladder has been reported in infants.

Applications of Misoprostol

Obstetrics

1.Cervical Ripening and labour induction.

2.Labour induction for postdated pregnancy

3.Labour induction in cases of second and early third trimester termination of pregnancies associated with fetal anomalies.

4.Labour induction in cases of intrauterine fetal death.

5.Management of spontaneous abortion.

6.Management of missed abortion.

7.Medical abortion:alone, or in combination with mifepristone / methotrexate.

8.Management of cervical pregnancy.

9.Cervical priming prior to surgical abortion.

10.Management of uterine atony leading to pospartum haemorrhage.

Mifepristone or RU-486

It is the anti-progestin approved for use in termination of pregnancy. The drug helps in two ways

(i) by causing cervical dilatation and reducing its resistance to dilatation.

(ii) By increasing the sensitivity of uterus to exogenous prostaglandins and thus shorten the induction abortion interval, increase the successful termination of pregnancy and reduce the total dose of PG required.[17-20]

Complications associated with medical termination of pregnancy

Incomplete abortion

Patients who underwent medical termination of pregnancy (TOP) were more likely to have retained products of conception requiring operative intervention. It was as high as 21% in some studies. Though it was less with misoprostol, the complication was higher than in patients who had surgical abortion (22% versus 4%)[21]

60% of subjects passed the placenta spontaneously within 2hrs, with approximately two-thirds of expulsions occurring in the first 30min. Retained tissues can lead to hemorrhage and infection.

Infection : During the 2nd trimester, infection rates for both medical and surgical termination of pregnancy remain in the range of 0.4-2%.[21, 22] The cervix should be cultured for gonorrhea and Chlamydia, ascending genital tract infections which are polymicrobial. Routine antibiotic prophylaxis may prevent upto half of all infections.[23, 24]

Failure of Medical termination of pregnancy: defined as a failure to achieve Termination of pregnancy [TOP] in 24-48hrs.

Uterine rupture: Serious complications including uterine rupture,[25, 26] major hemorrhage and cervical tear are rare. The incidence of uterine rupture is 0.2% in 2nd trimester. Risk factors include previous caesarean delivery, grand multipara, advanced gestation, prolonged PG therapy and use of oxytocin in addition to PG's.

Live birth: Second trimester medical TOP with PG analogues has been associated with live birth rates of 4% to 10%.[27] Physicians should have a protocol to induce fetal death before induction.

Bougie

Bougie was once a popular method but with the advent of better methods has lost some of its popularity. Still it is being used in some places, particularly in areas where the resources are scarce, due to its economy, comparatively good success rate and minimal complications.

This causes expulsion of the fetus by

i) Causing mechanical irritation of the uterus leading to myometrial contraction

ii) It also separates the membranes from the uterus.

iii) It causes reflex release of oxytocin.

iv) There is also release of lysosomal hydrolytic enzymes from the decidual cells, which elevate the PG precursor acids such as arachidonic acid from membrane phospholipid synthesis. Thus, release of PG occurs, resulting in uterine contractions.

Bougie is an inert substance devoid of any systemic complication, and being soft and atraumatic it will not damage the cervix or lower segment.

REVIEW OF LITERATURE

- Misoprostol is a PGE_1, analogue, produced and used since 1991 by Searle, to prevent peptic ulcer disease induced by NSAID's.[11-12]
- Von Euler (1935) found prostaglandin as an abortifacient.
- The total systemic bioavailability of vaginally administered misoprostol in 3 times more than orally administered misoprostol. (Ziemann, Fong. S.K., Benowitz NL, Banskter D, Darney PD – 1997).[16]
- In a comparative study of oral and vaginal misoprosol in 2nd trimester termination, 90% of vaginal group aborted in 48hrs and 69% of oral group aborted in 48 hrs (K.S.Wong, C.S.W Ngai, E.L.W. Yeo, L.C.H Tang and P.C.Ho, obstetrics and gynaecology 1997).
- Carbonelle et al – 1999 studied the effect of moistening of misoprostol before vaginal application and found it produced no improved efficacy.
- Acetic acid was used to dissolve misoprostol, to study the effect of acidic medium on the efficacy of misoprostol in 2nd trimester and found no improved outcomes. (B. Yilmaz S. kelechi, F.E. Ertas et al; Human Reproduction;Nov 1 2005; 20 (11): 3067 – 3071).

- Effect of vaginal PH on the efficacy of misoprostol: Vaginal PH does not appear to influence the efficacy of intravaginal misoprostol – Patrick ; Paul L ;et al (2000)

- Misoprostol is uterotonic and provides an effective alternative to other methods of midtrimester termination – Del Valle et al 1996.

- Misoprostol is over 70% effective in terminating pregnancy within 48 hrs, when used in second trimester – ACOG 2005, Medical management of abortion, ACOG practice bulletin No: 67 ; O & G 106 (4);871-872.

- A regimen using a combination of mifepristone 200mg and vaginal misoprostol (600-800 mcg as first dose) and oral misoprostol (400mcg every 3hrs for 4 doses) gave the highest complete abortion rate (97%) and shortest induction abortion interval (6.5 hrs) Elrafaey et al[19] 1995 and Ashok et al, 1999.

- Cervical ripening – value of intracervical tents in regimens using misoprostol is less clear. Jain.JK, Mishell Dr.Jr:- A comparison of misoprostol with and without laminaria tents for induction of second trimester abortion. Am. J. Obstretrics and Gynaec 1996; 175:173-177.

- When mifepristone pretreatment was used before vaginal misoprostol, the abortion rate was 90% is 24hrs and induction abortion interval was 9

hrs – Ho et al;[17] 1997 – Induction of abortion in the second trimester by a combination of mifepristone and misoprostol.

- In a randomised controlled trial to compare the effectiveness of 6 and 12 hrly administration of vaginal misoprostol for second trimester pregnancy termination Herabutya Y. Chanrachakul B, et.al. 2005 reported misoprostol (600 mcg) administered at 12 hour intervals was associated with fewer adverse effects and was as effective as 6 hour interval and there was no significant difference in the mean induction to abortion interval at 6 hours (16 hours) and 12 hours (16 hours).

- In the study by Snehamay Chaudhuri et al. 2006, the efficacy of 400 mcg. of tablet misoprostol inserted in the vagina every 12 hours for a maximum of 4 doses was compared with extraamniotic ethacridine lactate for second trimester MTP. The mean induction to abortion interval was shorter in microprostol group (15.5 hours) and rate of successful abortion within 48 hours was 95%.

- Women who did not abort within 48hrs (10%) required further interventions. either PGE2 vaginal suppositories, PGF2 alpha inj,.D & E, oxytocin infusion – John .K, Jain MD, Joh, Kero and Daniel R. Mishell, Jr.MD – 1999.

- Routine antibiotic prophylaxis may prevent up to half of all post – TOP infections and is highly cost effective – Sawaya GF, Grady D, Kerlihowshik, et al:[23] antibiotics at the time of induced abortion. The case of universal proplylaxis based on meta analysis. Obstetrics & Gynaec 1996; 87:884-890.

- Jacot F & M, Poulin C, Bilodeau AP, et al[28] 1993, reported no increase in complication rate as compared to 1st trimester abortion, in a 5 year experience with second trimester induced abortion.

- Retained placenta (incomplete abortion) requiring operative intervention was common with misoprostol termination of pregnancy – 22% than with surgical method of termination. Textbook – High risk pregnancy – Management options: D.K. James; P. J.Steer.

- The use of misoprostol in 2nd trimester abortion in women with prior caesarean delivery was not associated with an excess of complications compared with women with unscarred uteri – Jan. E. Dickinson.M.D-ACOG 2005;105:352-356.

- Chen. M, Shih. JL, Chin. WT, Hsieh. FJ; reported separation of caesarean scar during 2nd trimester intravaginal misoprostol abortion; obstetrics & Gynaec 1999-94-840.

- There is good conception rates postabortally with use of misoprostol C.Reinun MD 1999.

- Boorn and Gustive[29] in 1974 studied & found that myometrial activity can be initiated by mechanical stimulation of uterus.

- Extra ovular placement of rubber tube was advocated by George (1979) for midtrimester abortion with prolonged IA interval being the major problem.

- Midtrimester abortion was induced with No12 rubber catheter; 96% aborted within 40 hours: Dr. Rajan & Dr. K.R. Usha 1979.

- Extra ovular rubber catheter for midtrimester, abortion was used with success by Gaurad 1979.

- Saxena S.C. and Sharma[30] 1980 have studied termination of pregnancy using rubber catheter and Ryle's tube in 70 cases with 86.9% success rate.

- In a study of 200 cases between 14-22 weeks, midtrimester abortion was induced using rubber catheter and success rate of 90% has been reported by J. Mishra and Rita Kumari 1981.

- There has been a resurgence in catheter based techniques and they are found to be effective for cervical ripening. Shuman D.J.,

Frenkel . E, Tovbin. J et al[31.] Ripening of the unfavourable cervix with extra amniotic catheter; Clinical experience a review. obstet and Gynaec survey 1996; 51; 621-627.

- Anitha Singh and Shanthi Roy[32] 1985 in their study of 75 patients using rubber catheter for 2nd trimester abortion, reported a success rate of 92%.

AIM OF THE STUDY

To compare the relative efficacy of vaginal misoprostol and extra amniotic bougie in second trimester abortion and to compare the

(i) Induction abortion interval

(ii) Complete abortion rate and

(iii) Success rate between the two methods.

MATERIALS AND METHODS

The study was conducted at Institute of social obstetrics – Government Kasturba Government Gandhi Hospital, Chennai, in the family welfare department. 100 women who came for second trimester abortion were randomized to receive 400 mcg of misoprostol every 12 hours for a maximum of 4 doses and another 100 patients were subjected to termination by extra amniotic Bougie insertion.

Inclusion Criteria:

- 14 – 20 weeks of Pregnancy
- Women fulfilling indications for MTP according to MTP act.
- No other medical/surgical complications

Exclusion Criteria:

- History of previous uterine surgery (i.e) myomectomy or Caesarean section
- Uncontrolled seizure disorder
- Cardio vascular disease
- Glaucoma
- Pulmonary, hepatic or renal disorders
- Allergy to misoprostol or other prostaglandins

Patient assessment

This includes history, physical examination, appropriate laboratory studies and counselling.

History:

- Menstrual history & last menstrual period
- Past reproductive history, sexual history
- Prior pelvic surgery and any known uterine anomalies.
- Current medical illness, medications and allergies

Physical examination :

- Vital signs, weight, height and cardio pulmonary status was recorded in every patient
- Speculum examination was done to rule out local cervical pathology
- Bimanual examination was done to assess the uterine size

LABORATORY STUDIES: The following were done in all patients

- Complete Haemogram
- Blood grouping and typing
- urine analysis
- Screening for common sexually transmitted disease – TV, Moniliasis , HIV & VDRL

- Blood sugar, urea,
- ECG and anaesthetic fitness were obtained for patients who opted for permanent family planning measures with the MTP.
- Ultrasound was done in all cases for accurate determination of gestational age, placental location and presence of uterine anomalies.
- Inj T.T. and prophylactic antibiotics were given for all patients.

The patient was informed about the medication, abortion and the need for an operative intervention – D & C, in case of incomplete abortion was explained and a written consent was obtained. Risks of hemorrhage, hysterotomy, fever, vomiting and diarrhea associated with misoprostol were also addressed.

Method of misoprostol induction:

Under aseptic precautions, 400 mcg of misoprostol was kept in the posterior fornix. Further doses are withheld if there are uterine contractions or bleeding. Patients were observed in semi ICU & the following were noted.

- Time of induction
- 4^{th} hrly Temp, PR & BP
- Time of onset of contractions, rupture of membranes, bleeding

- Time of expulsion
- Time of repeat doses.
- Nature of abortion – complete / Incomplete
- Oxytocics needed
- D&C required for completion of abortion
- Maternal Complications – fever, pain, & vomiting were noted.

10U of oxytocin in 500 ml of RL and methyl ergometrine 0.2 mg iv was given to all patients after expulsion to prevent excessive bleeding.

In cases of incomplete abortion, the remaining products were removed manually or by curettage. Such of those who did not expel after 48 hours, were given high titre oxytocin or laminaria tent with oxytocin or PGE2 gel with oxytocin (ie. after 48 hrs-no uterine contraction, bleeding or the os is closed)

- USG was done for all patients before discharge

Bougie insertion:-

After ensuring the patient's bladder is empty, the patient in put in lithotomy position. Under aseptic precautions, Bougie was introduced extraamniotically. No anaesthesia was required. It was followed 24 hrs later by oxytocin infusion.

The patients were observed in semi ICU & the following were noted:

- The onset of uterine contractions, pain or vaginal bleeding.
- Time of expulsion.
- Nature of abortion/complete or incomplete.

10 U Oxytocin in 500ml of RL and 0.2mg iv methyl ergometrine were given to all patients to prevent excessive bleeding.

- In cases of incomplete abortion the products were removed by D& C.
- Patients who failed to expel after 48hrs were treated with either PGE2 gel intracervically or laminaria tent and high titre oxytocin.
- USG was done for all patients before discharge

In both methods of termination of pregnancy, patients who failed to expel with other methods also were taken for hysterotomy.

ANALYSIS OF STUDY

This is a randomized trial comparing the efficacy of intravaginal misoprostol to extra amniotic bougie insertion in second trimester MTP conducted at Institute of social obstetrics, Government Kasturba Gandhi hospital, Chennai during the period March 2006 – August 2007

100 patients received 400mcg of vaginal misoprostol every 12 hours up to a maximum of 4 doses

100 patients were subjected to termination of pregnancy by extra amniotic insertion of bougie. The results were subjected to statistical analysis using the Chi – square test.

Age distribution:- (Table -1)

Age in Yrs.	**Misoprostol regimen (n-100)**		**Bougie insertion (n=100)**	
	No of Patients	**%**	**No of Patients**	**%**
16-20	16	16%	4	4%
21-25	29	29%	32	32%
26-30	46	46%	49	49%

31-35	9	9%	15	15%

Both the groups were age matched to the extent possible though we preferred using misoprostol in the age group 16-20, since most of them were unmarried or primi.

Parity distribution:-

Parity	**Misoprostol regimen (n-100)**		**Bougie insertion (n=100)**	
	No of Patients	**%**	**No of Patients**	**%**
Nullipara	16	16%	5	5%
G-2	50	50%	56	56%
G-3	34	34%	31	31%
G-4	--	--	8	8%

Out of the 21 nullipara, 16 were subjected to misoprostol regimen, while in 8 patients who were gravida 4 and more, the pregnancy was terminated by extra amniotic bougie. More than 50% of the patients who came for second trimester termination were second gravida.

Distribution according to Gestational Age

Table -3

Gestational age in weeks	Misoprostol regimen (n-100)		Extra amniotic Bougie (n=100)	
	No of Patients	%	No of Patients	%
14-16	46	46%	10	10%
17-18	42	42%	57	57%
19-20	12	12%	33	33%

Indications for MTP

Table : 4

Indications for MTP	No. of Patients	%
Unmarried Pregnancy	21	10.5%
Unwanted Pregnancy	86	43%
Limiting the Family	60	30%
Failure of Sterilisation	4	2%
Medical Reasons	10	5%
Eugenic	2	1%
Others	17	8.5%

Most Common indication for MTP was unwanted pregnancies (43%)

Unmarried Pregnancies accounted for 10.5% in this study

MTP for pregnancies from failure of Sterlisation was done in 2%

Total dose of Misoprostol required for abortion

Table : 5

Total dose of Misoprostol (mcg)	Primi		Multi		Total	
	No.	%	No.	%	No.	%
400	6	37.5%	29	34.52%	35	35%
800	8	50%	32	38.09%	40	40%
1200	2	12.5%	11	13.09%	13	13%
1600	-	-	11	13.09%	11	11%

- 35 out of 100 patients expelled with a single dose of misoprostol.

- of the remaining, 40 patients expelled with 2 doses of misoprostol.

- 11 patients required maximum of 4 doses.

- 14 of 16 nullipara, expelled with 2 doses.

Comparison of Induction abortion interval between the groups in primi

Table: 6

Induction abortion interval in hrs	**Misoprostol regimen (n=16)**		**Bougie insertion (n=5)**		
	No of pts	**%**	**No of pts**	**%**	
<12	6	37.5%	-	-	x^2 – 13.1
12 - 24	8	50%	-	-	p value
24 - 48	2	12.5%	5	100%	0.001
>48	-		-	-	

- while 87.5% in the misoprostol group expelled in less than 24 hrs; all the patients in bougie group expelled after 24 hrs, the difference is statistically significant. (p value 0.001)

Comparison of Induction abortion interval between the groups in multi

Table: 7

Induction abortion interval in hrs	Misoprostol (n=84) regimen		Bougie (n=95) insertion		
	No of pts	%	No of pts	%	
<12	29	34.52%	2	2.10%	x^2 – 56.9 p value 0.00
12 - 24	32	38.09%	16	16.84%	
24 - 48	18	21.42%	56	58.94%	
>48	4	4.76%	18	18.94%	

- While 72.61% of multi in the misoprostol regimen expelled in less than 24 hrs, 77.88% of multi in the bougie group expelled between 24 – 48 hrs, with a statistically significant difference.

- 1 in the misoprostol regimen and 3 in the bougie group; who failed to expel even with other methods were taken for hysterotomy.

Comparison of the Average induction abortion interval between the groups

Table : 8

IA interval (hrs)	Mode of Termination	Total no. of patients		Average IA Interval (hrs)		
		Primi	**Multi**	**Primi**	**multi**	
<24 hrs	Misoprostol	14	61	13.76	13	Primi x^2-13.1 p 0.00 Multi x^2-42.8 p value 0.00
	Bougie	-	18	-	21.07	
24-48 hrs	Misoprostol	2	18	25.65	23.47	
	Bougie	5	56	36.12	36.50	

- In patients who expel within 24 hrs in the misoprostol group, the average IA interval in Primi is 13.76 hrs; and 13 hrs in multi

- For patients who expel between 24-48 hrs, the average IA interval in misoprostol group is 25.65 hrs and 23.47 hrs in Primi and Multi respectively, while in the bougie group it is 36.12 hrs and 36.50 hrs in primi and multi respectively

Comparison of the nature of abortion between the groups

Table: 9

Mode of termination	**Complete abortion**		**Incomplete abortion**		
	No of Patients	**%**	**No of Patients**	**%**	
Misoprostol regimen	79	79%	16	16%	x^2 6.3 p value 0.01
Extra amniotic Bougie	52	52%	27	27%	

5 patients in the Misoprostol group & 21 patients in the bougie group, had to have additional methods like high titre oxytocin, laminaria tent, PGE_2 gel or hysterotomy since they did not expel even up to 48 hrs of bougie/1600mcg of misoprostol

Comparison of success rate between the groups

Table: 10

Mode of termination	Success rate	Failure rate	
Misoprostol regimen	95	5	x^2-11.3 p value 0.001
Extra amniotic bougie	76	21	

Thus misoprostol has statistically significant abortion rate at 48 hrs over the bougie method of termination.

Success and failure rate in relation to parity with misoprostol regimen

Table : 11

Parity	Total no of pts	Successful abortion	Failure	Success rate	Failure rate
Primi	16	16	-	100%	-
G2	50	47	3	94%	6%
G3	34	32	2	94.12%	5.88%

- Criteria for failure were when expulsion did not occur within 48 hrs of insertion of bougie or with 1600mcg of misoprostol.

- In 4 women, expulsion resulted following high titre oxytocin infusion

- In 1 woman, hysterotomy was done when additional measures like high titre oxytocin failed.

Success and failure rate in relation to parity with extra amniotic bougie

Table : 12

parity	Total no of pts	Successful abortion	Failure	Success rate	Failure rate
Primi	5	5	-	100%	-
2	56	44	12	78.57%	21.42%
3	31	24	7	77.42%	22.58%
4 and >	8	6	2	75%	25%

Comparing the groups, in gravida 2

x^2-5.2; p value 0.02,

Gravida 3: x^2-4.2; p value 0.04.

- 18 of the 21 failure cases expelled with other methods

- 8 with high titre oxytocin infusion

- 6 with PGE_2 gel and oxytocin infusion

- 4 with laminaria tent and oxytocin infusion

- 3 patients who failed to respond to alternative methods were taken for hysterotomy.

Comparison of success and failure rate in relation to gestational age

Table : 13

GA in weeks	Method of termination	No. of pts	Successful abortion	Failure	Success rate	Failure rate
14-16	Misoprostol	46	46	-	100%	-
	Bougie	10	8	2	80%	20%
17-18	Misoprostol	42	38	4	90.48%	9.52%
	Bougie	57	44	13	77.20%	22.80%
19-20	Misoprostol	12	11	1	91.66%	8.34%
	Bougie	33	27	6	81.82%	18.18%

Result comparing the groups in relation to Gestational Age

Table : 14

GA in weeks	x^2 value	p value
14-16	9.5	0.002
17-18	3.0	0.08
19-20	0.65	0.42

The success rate at 14-16, 17-18 and 19-20wks, were 100%; 90.48% and 91.66% respectively with misoprostol regimen, while they were only 80%; 77.20% and 81.82% respectively with bougie; though the difference is statistically significant only at 14-16wks.

Complications with misoprostol regimen.

Table : 15

Complication	No of patients	%
Pain	22	22%
Fever	9	9%
Vomiting	7	7%
Blood transfusion	-	-

The most common side effects noted with misoprostol were

(i) crampy lower abdominal pain

(ii) vomiting

Complications with extra amniotic bougie

Table : 16

Complication	No of pts	%
Fever and other signs of sepsis	5	5%
Bleeding requiring transfusion	-	-

- 5 patients developed fever and foul smelling vaginal discharge and were treated with higher antibiotics.

- Blood transfusion was not necessary for any of the patients in either of the groups.

DISCUSSION

This is a randomized trial comparing the efficacy of Intravaginal misoprostol to the extra amniotic bougie insertion with100 patients in each group who sought MTP at Institute of Social Obstetrics and Government Kasturba Gandhi hospital , Chennai .

The results of this study are discussed as follows:

In the study by John.K.Jain et al[33] comparing the efficacy of 200mcg of misoprostol every 6 or every 12hrs; the mean age was 28.4 years. In this study the average age was 28yrs(TABLE-1)

The mean parity in this study was 2.6; and this is comparable to the study by Daniel.R..Mishell, John.K.Jain[33] where the mean parity was 2.8.(Table-2)

Most common indication for MTP in this study was unwanted pregnancies.

TERMINATION WITH MISOPROSTOL Misoprostol has many advantages over other PGs. It is less expensive and does not require refrigeration for storage as with Gemeprost. Though misoprostol is being widely used in I trimester MTP with or without mifepristone as a standard operative protocol, there is no such protocol for use of misoprostol in second trimester MTP.

Various dosage regimens are being tried with varied success.

Dose	**Dosage Interval**	
400mcg	12th hrly	In this study
400mcg	12th hrly	Snehamay chaudhari et al[34], 2007
400mcg	12th hrly	Herabutya y, Punyavachira et al 2003
400mcg	6th hrly	K.S. Wong; C.S.W.Ngai et al[35] 2000
400mcg	6th hrly	G.Novab, M.N.Helw 1998
400mcg	Every 3 hrs for a maximum of 5 doses	k.S.Wong; C.S.W.Ngai; P.C.Ho[35]-2000
600mcg	12th hrly	Herabutya Y Chanrachakul et al 2000
200mcg	12th hrly	Herabutya Y; Chanrachakul et al 2000
200mcg	6th hrly/ 12th hrly	John.K.Jain,M.D,John Kuo and Daniel R.Mishell JR M.D[33]-1999

In this study, the average induction abortion interval for all gestational age is 18.17 Hrs.

This is comparable to the result in various studies for all gestational ages.

Dose	**Average IA Interval**	
400mcg 12th hrly	15.5hrs	Snehamay chaudhari et al[34], 2007
400mcg 12th hrly	16hrs	Herabutya y, Punyavachira et al[36] 2005
200mcg 12th hrly	14hrs	John.K.Jain,M.D,John Kuo and Daniel R.Mishell JR M.D[33]-1999
600mcg 12th hrly	24.1hrs	Herabutya Y; Chanrachakul 2000
200mcg 12th hrly	27.5hrs	Tong Sung et al 1997
400mcg 12th hrly	16.9hrs	G.Novab, M.N.E.L. Helw et al 1998

In this study, 75% of the patients expelled with less than 800mcg; Most of the primi (87.5%) expelled with an average dose of 628.5mcg and most of the multi (72.61%) expelled with an average dose of 609.8mcg. This is in comparison to the study by Snehamay chaudhari et al[34] 2007, using 400mcg of

intravaginal misoprostol every 12 hrs, with the average dose of 760mcg of misoprostol.

The maximum dose in this study was 1600mcg which was required in 11 women; comparatively similar average dose of 2000mcg was used in the study By C.S.W.Ngai et al[35] 2000; and also showed that up to 4000mcg over 48hrs was well tolerated.

While the complete abortion rate in this study is 79%, the same in various studies are as follows.

Dose	**Complete Abortion Rate**	**Study**
200mcg 12th hrly	80%	Srisomboon J; Tongsung.T et al 1997
200mcg 12th hrly 400mcg 12th hrly 600mcg12th hrly	65% 72% 78%	Herabutya Y ; Chanrachakul et al 1998
400mcg 6th hrly	85%	G.Novab; M.N.E.L.Helw et al1998
400mcg 3rd hrly	80%	Wong.K.S;Ngai.N.S et al[35] 1998
200mcg6th hrly	83%	Herabutya.Y; Punyavachira et al 1997

MTP was considered successful when there was complete evacuation of the pregnancy in 48 hrs. it was noted in 95% in this study. The success rates in various studies are as follows

Dose	Success Rate	Study
400mcg 12th hrly	82%	Herabutya et al; 1998
600mcg 12th hrly	92%	Herabutya et al[36]; 2005
400mcg 12th hrly	95%	Snehamay chaudhari et al[34]; 2006
600mcg 12th hrly	90%	Herabutya et al 1998
200mcg 12th hrly	92%	Nuutila et al[37]; 1997
200mcg 12th hrly	89%	Jain and Mishell et al[33]; 1999

MTP was considered a failure, if expulsion did not occur with in 48 hrs; of the 5 patients who failed to expel in our study; 4 patients expelled with high titres oxytocin and in 1 patient who did not expel even with other methods, hysterotomy was resorted to. The success rate at 14-16 wks, 17-18 weeks, 19-20weeks were 100%; 90.48% & 91.66% respectively comparable to that in the study by Snehamay Chaudhari et al[34] 2006 where in the success rates were 100%; 88.88% 83.33% at 14-16; 17-18, 19-20 weeks respectively.

Analgesia was required in 22% of women who had abdominal pain in this study, whereas in other studies, the complication rates were higher.

- 49% in the study by John .K. Jain et al[33] 1999
- 36.5% in the study By K.S.Wong; C.S.W.Ngai et al[35] 2000.
- Fever was seen in 9% of patients similar to that reported by John.K.Jain et al[33] 1999 where it was 8%
- Vomiting was reported in 15% of patients by Snehamay Chaudhari et al[34] 2006%; but in this study it was only 7%.
- In this study no women required blood transfusion and in other studies by K.S.Wong; C.S.W.Ngai et al[35] 2000; John.K.Jain, John Kuo et al[33] 1999; Snehamay chaudhari et al[34] 2006, the blood loss was less than 500ml and no women required blood transfusions.

TERMINATION BY EXTRA AMNIOTIC BOUGIE:

- With this method, only 18% expelled in less than 24hrs with an average induction abortion interval of 21.07hrs, while 61% expelled between 24-48 hrs, with an average induction abortion interval of 36.12hrs in primi and 36.50hrs in multi .
- The success rate in 48hrs is 79% in this study. Saxena.S.C. and Sharma.S[30] in 1980 have showed a success rate of 86.9% with rubber catheter
- In this study, 5% of the patients had fever with signs of sepsis and this is similar to 5.8% infection rate reported by Saxena.S.C and Sharma.S[30] in 1980

Though medical abortion has largely replaced bougie, there is still a place for extra amniotic bougie particularly in resource poor settings where the affordability of medical abortion is low. However, bougie should be considered only as a last measure when other techniques are available. The limited use of this once very popular technique has resulted in paucity of authentic studies in the recent past.

SUMMARY

- The average age was 28 years and the mean parity in this study was 2.8
- Most common indication for MTP in this study was unwanted pregnancies
- There is a statistically significant difference in the induction abortion interval between the misoprostol and bougie groups in both primi [p.value-0.001] and multi(p value -0.00)
- Similarly the abortion rate at 24hrs was also found to be statistically significant in both primi(0.00) and multi [o.oo]
- The abortion rate was 75% in 24hrs in the misoprostol group whereas it was only 18% in the bougie group.
- The difference between these methods with regards to the success rate was also found to be statistically significant (0.01) being 95% with misoprostol regimen. Where as it was 79% with extra amniotic bougie.
- The difference between the methods as regards the completion of abortion was also statistically significant (p value 0.01) being 79%

with misoprostol regimen, whereas it was only 52% with extra amniotic bougie

- The success rate at 14-16 weeks with misoprostol was 100% whereas it was 80% with bougie, the difference is statistically significant (p value-0.02); the difference at other gestational age was not statistically significant

- The out come was not influenced by parity

CONCLUSION

This study comparing the efficacy of 400mcg of intravaginal misoprostol every 12 hrs to the extra amniotic bougie in second trimester MTP conducted at Institute of social obstetrics, Government Kasturba Gandhi Hospital Chennai, 400mcg intravaginal misoprostol every 12 hrs has a better out come in terms of

(i) Shortened induction abortion interval

(ii) Increased abortion rate at 24 hrs

(iii) High success rate

(iv) Increased complete abortion rate

Overall misoprostol 400mcg has been found to be a safe, efficacious and an affordable method of second trimester MTP

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PROFORMA

S. No

NAME: AGE: IPNO: OCCUPATION:

SOCIOECONOMIC STATUS: EDUCATIONAL STATUS:

MARITAL STATUS:

MARRIED/UNMARRIED/DIVORCEE/WIDOW/DESERTED

GRAVIDA: PARA: LIVE: ABORTION:

M/H: LMP: LCB:

GA:

INDICATION FOR TERMINATION:

PREVIOUS OBSTETRIC HISTORY:

RELEVANT MEDICAL/SURGICAL HISTORY:

PAST HISTORY

GENERAL EXAMINAION:-

PR: BP: ANAEMIA: PEDAL OEDEMA;

CVS HT: WT: THYROID

RS:

OBSTETRIC EXAMINATION:

PER ABDOMEN: UTERINE SIZE

FP

SPECULUM EXAMINATION:-

PER VAGINAL EXAMINATION:

INVESTIGATION:

COMPLETE HAEMOGRAM

URINE: ALBUMIN, SUGAR, DEPOSTS

BLOOD GROUPING AND TYPING

VDRL, HIV (AFTER GETTING CONSENT FROM THE ABORTION SEEKER)

SMEAR : TV, MONLIASIS

BLOOD SUGAR:

UREA:

ECG

USG

Mode of Termination:

Misoprostol

Initial Dose

Number of doses repeated

Time of onset of contractions

Bleeding or rupture of membranes

Nature of abortion

Time of expulsion

Induction abortion interval

Mode of termination-vaginal/Hysterotomy

Oxytocics needed

D and C

Maternal Complications

Extra Amniotic bougie insertion

- Time of insertion of bougie
- Time of onset of contractions,
- Bleeding or rupture of membranes
- Time of expulsion
- Induction abortion interval
- Mode of termination-Vaginal / Hysterotomy
- Oxytocics needed
- D and C
- Maternal complications